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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------|--------------------|----------------------|---------------------|------------------|
| 08/252,384 | 06/01/1994 | C. STEVEN MCDANIEL | TAMK145 | 3543 |
| 27922 7 | 590 05/05/2005 | | EXAMINER | |
| C. STEVEN MCDANIEL | | | PAK, YONG D | |
| MCDANIEL & | & ASSOCIATES, P.C. | | | |
| P.O. BOX 2244 | | | ART UNIT | PAPER NUMBER |
| AUSTIN, TX 78768 | | | 1652 | |

DATE MAILED: 05/05/2005 ·

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|--|--|--|--|--|--|--|
| | 08/252,384 | MCDANIEL ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Yong D. Pak | 1652 | | | | |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a repl - If NO period for reply is specified above, the maximum statutory period or - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing - earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be tim y within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from t, cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>17 June 2003</u> . | | | | | | |
| | | | | | | |
| 3) Since this application is in condition for allowa | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>73-82</u> is/are pending in the applicatio | n. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| | 6)⊠ Claim(s) <u>73-82</u> is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/o | r election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)☐ The oath or declaration is objected to by the Ex | caminer. Note the attached Office | Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. | | | | | | |
| 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau | | - www. | | | | |
| * See the attached detailed Office action for a list | of the certified copies not receive | d. | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) | (PTO-413) te. | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | | atent Application (PTO-152) | | | | |

Art Unit: 1652

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DETAILED ACTION

This application is a continuation of 07/928,540, now abandoned, which is a divisional of 07/344,258, now abandoned.

Continued Examination Under 37 CFR 1.114

The request for a continued prosecution application (CPA) under 37 CFR 1.53(d) filed on June 17, 2003 is acknowledged. 37 CFR 1.53(d)(1) was amended to provide that the CPA must be for a design patent and the prior application of the CPA must be a design application that is complete as defined by 37 CFR 1.51(b). See *Elimination of Continued Prosecution Application Practice as to Utility and Plant Patent Applications*, final rule, 68 Fed. Reg. 32376 (May 30, 2003), 1271 Off. Gaz. Pat. Office 143 (June 24, 2003). Since a CPA of this application is not permitted under 37 CFR 1.53(d)(1), the improper request for a CPA is being treated as a request for continued examination of this application under 37 CFR 1.114.

The amendment filed on May 21, 2003, canceling claims 17-29, 34-36 and 41-72 and adding claims 73-82, has been entered.

Claims 73-82 are pending and are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Page 2

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 73-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 73-82 are drawn to a polynucleotide having the nucleotide sequence of SEQ ID NO:1, the encoded polypeptide having the amino acid sequence of SEQ ID NO:2 and vectors and host cells comprising said polynucleotide. However, the polynucleotide encoding the polypeptide of SEQ ID NO:2 of claims 73-82 were not described in the application as originally filed nor in any of its parent applications. The specification as filed contains disclosure of a polynucleotide encoding an organophosphorus acid anhydrase which is different from the organophosphorus acid anhydrase of SEQ ID NO:2 submitted in the Sequence Listing filed on May 21, 2003. Therefore, claims 73-82 contain new matter.

Given this lack of description of the polynucleotide encoding the polypeptide of SEQ ID NO:2 and vectors and host cells comprising said polynucleotide in the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 73-82 at the time of filing of the instant application.

Art Unit: 1652

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 73-75 and 77-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Serdar et al.

Claims 73-75 and 77-81are drawn to a polynucleotide having the nucleotide sequence of SEQ ID NO:1, the encoded polypeptide having the amino acid sequence of SEQ ID NO:2 and vectors and host cells comprising said polynucleotide.

Serdar et al. (U.S. Patent No. 5,484,728 – form PTO-892) discloses a polynucleotide encoding a processed or mature anhydrase of 337 amino acids, consisting of a Met residue and residues 30-365 of the sequence in Figure 6, which has 100% sequence identity to the polynucleotide of SEQ ID NO:1 of the instant invention (See sequence alignment and claims 1-8 of Serdar et al.). Serdar et al. also discloses

Art Unit: 1652

vectors and host cells comprising said polynucleotide (Columns 7-15 and claims 1-8). Therefore, the reference of Serdar et al. anticipates claims 73-75 and 77-81.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 76 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Serdar et al. in view of Wong et al.

Claims 76 and 82 are drawn to a viral vector and a mammalian cell comprising a polynucleotide encoding SEQ ID NO:2.

Art Unit: 1652

Serdar et al. teaches a polynucleotide encoding SEQ ID NO:2, as discussed above.

The reference of Serdar et al. does not teach a viral vector or a mammalian cell comprising the polynucleotide.

However, viral vectors and mammalian host cells for the expression of heterologous proteins is well known. Wong et al. (U.S. Patent No. 4,849,355 – form PTO-892) discloses viral vectors and mammalian host cells comprising a heterologous polynucleotide (Columns 3-4 and claims 1-10).

Therefore, combining the teachings of Serdar et al. and Wong et al., it would have been obvious to one having ordinary skill in the art make a viral vector or mammalian host cell comprising the polynucleotide of Serdar et al. One of ordinary skill in the art would have been motivated to make such a construct to express heterologous proteins in a mammal. One of ordinary skill in the art would have had a reasonable expectation of success since Wong et al. teaches how to make such a construct and successfully express heterologous proteins in mammals.

Therefore, the above references render claims 76 and 82 *prima facie* obvious to one of ordinary skill in the art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned

Art Unit: 1652

are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak Patent Examiner 1652

Manjunath Rao

Primary Examiner 1652

Page 7